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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/032,108	12/20/2001	Timothy David Osslund	01017/38834F	7916

7590 05/19/2004

U.S. Patent Operations/MWK
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EXAMINER

BASI, NIRMAL SINGH

ART UNIT	PAPER NUMBER
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1646

DATE MAILED: 05/19/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/032,108	OSSLUND, TIMOTHY DAVID	
	Examiner	Art Unit	
	Nirmal S. Basi	1646	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on 20 June 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 60 and 61 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) 60, 61 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 20 December 2001 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>6/20/03, 12/20/01</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restriction

1. The Restriction Requirement mailed 11/19/03 is withdrawn. Upon further review it has been noted claim 1 was cancelled in the Amendment filed 12/20/2001, and claims 2-59 cancelled in the Transmittal of New Application filed 12/20/2001, claims 60 and 61 were added in the Amendment filed 12/20/2001. No restriction is required between claims 60 and 61. Therefore claims 1-59 have been cancelled and claims 60, 61 are pending and will be examined.

Drawings

2. New corrected drawings are required in this application for the reason given below. Applicant is advised to employ the services of a competent patent draftsman outside the Office, as the U.S. Patent and Trademark Office no longer prepares new drawings. The corrected drawings are required in reply to the Office action to avoid abandonment of the application. The requirement for corrected drawings will not be held in abeyance.

The drawings are objected to as failing to comply with 37 CFR 1.84(p)(4) because: a) reference character "FIG. 3A", "FIG.3B", "FIG. 3C", "FIG. 3D" have been used to designate both a figure number and parts of a figure. It is suggested, to overcome the objection, the figure be labeled as FIG. 3 and the parts labeled as A, B, C and D; b) reference character "FIG. 4A", "FIG.4B", "FIG. 4C", "FIG. 4D" and "FIG 4AB, have been used to designate both a figure number and parts of a figure. It is

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suggested, to overcome the objection, the figure be labeled as FIG. 4 and the parts labeled as A, B, C, D and 4AB

Specification

3. The disclosure is objected because of the following informalities and appropriate correction is required:

In the specification, Figure 5 must be describes as FIGURES (5A-5VV) and not FIGURES 5 (1-41), or the equivalent, as required by 37 C.F.R. § 1.84 (u)(1).

Sequence Rules Compliance

4. This application fails to comply with the sequence rules, 37 CFR 1.821-1.825.

Nucleotide and polypeptide sequences must be identified with the corresponding SEQ ID NO. Title 37, Code of Federal Regulations, Section 1.821 states "reference must be made to the sequence by use of the assigned identifier", the identifier being SEQ ID NO. Claims refer to Figure 1 to disclose an amino acid sequence. All sequences in the claims must be identified by their corresponding SEQ ID NO:. Correction is required.

Claim Rejection, 35 U.S.C. 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 60-61 are rejected under **35 U.S.C. 112, second paragraph**, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 60 is indefinite because it is ambiguous as to the lysines, which are "altered". Specifically, which lysines are included in the term "include" so as to allow the metes and bounds of the claim to be determined? It is not clear if altered, in subsection (b), means attaching polyethylene glycol molecules to the lysines present in the AB loop and CD loop of the polypeptide of SEQ ID NO: 2, disclosed in Figure 1, or if altered also includes attaching polyethylene glycol molecule to lysines which may be additionally substituted into the AB loop and CD loop of the polypeptide of SEQ ID NO: 2. The claim is further ambiguous because it is not clear if the claimed G-CSF analog differs from the amino acid sequence disclosed in Figure 1 by containing other additions and/or subtractions, in addition to having lysines 17, 35 and 41 substituted with arginine, optionally containing an N-terminal methionine and the alteration in part (b). It is suggested, to overcome the rejection, the claim, be amended to specifically state that the claimed G-CSF analog only differs from that disclosed in SEQ ID NO:2 by optionally containing an N-terminal methionine, and only the differences claimed in subsections (a) and (b). It is further suggested, to overcome the rejection, the claim in section "(b)", be amended to include language such as "the lysines present in the AB loop and CD loop of the G-CSF disclosed in SEQ ID NO: 2 are altered to include at least one polyethylene glycol molecule".

Claim 61 is indefinite because it is ambiguous as to the lysines, which are "altered". Specifically, which lysines are included in the term "include" so as to allow the metes and bounds of the claim to be determined? It is not clear if altered means attaching polyethylene glycol molecules to the lysines present in the AB loop, BC loop

and CD loop of the polypeptide of SEQ ID NO: 2, disclosed in Figure 1, or if altered also includes attaching polyethylene glycol molecules to lysines which may be additionally substituted into the AB loop, BC loop and CD loop of the polypeptide of SEQ ID NO: 2. The claim is further ambiguous because it is not clear if the claimed G-CSF analog differs from the amino acid sequence disclosed in Figure 1 by containing other additions and/or subtractions, in addition to having lysines 17, 35 and 41 substituted with arginine, optionally containing an N-terminal methionine and the alteration in part (b). Also, the use of the word "last", in subsection (b), renders the claim indefinite. It appears there has been a typographical error, should "last" be "least"? It is suggested, to overcome the rejections, the claim, be amended to specifically state that the claimed G-CSF analog only differs from that disclosed in SEQ ID NO:2 by optionally containing an N-terminal methionine, and only the differences claimed in subsections (a) and (b). It is further suggested, to overcome the rejection, the claim, in section "(b)", be amended to include language such as "the lysines present in the AB loop, BC and CD loop of the G-CSF disclosed in SEQ ID NO: 2 are altered to include at least one polyethylene one glycol molecule".

5. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

US Patent 4904584, site-specific homogeneous modification of polypeptides, issued Feb 27 1990, discusses G-CSF and modification (pegylation) of lysine residues 16, 23, and 34.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nirmal S. Basi whose telephone number is 571-272-0868. The examiner can normally be reached on 9:00 AM-5:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz can be reached on 571-272-0887. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Nirmal S. Basi
Art Unit 1646
May 17, 2004

NSB


LORRAINE SPECTOR
PRIMARY EXAMINER